elf atochem

Contains No CBI

ELF ATOCHEM NORTH AMERICA, INC.
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(A)

8EHQ-92-12672
8892001085 1
INIT

October 12, 1992

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP Identification Number: 8ECAP-0026

Dear Sir/Madam:

Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and Environmental Protection Agency (EPA), Atochem is submitting the enclosed final report on a study to establish skin irritation potential in rabbits to the EPA. This study does not involve effects in humans.

Nothing in this letter or the enclosed study is considered confidential business information of Atochem.

The enclosed study provides information on the chemical tetraethyltin. Its exact chemical name is tetraethyl stannane and its CAS number is 597-64-8.

The title of the enclosed study is Primary Skin Irritation Study in Albino Rabbits with Tetraethyltin With Washoff. The following is a summary of the adverse effects observed in this study.

One-half (0.5) ml of tetraethyltin was applied to both an intact and abraded skin site on each of six albino rabbits for 5 minutes followed by a 15-minute washoff period. All six rabbits died within 18 hours of test material application.

mm
2/9/95

Atochem previously submitted a TSCA Section 8(e) notice on tetraethyltin. The submission was made July 31, 1992; we have not been notified by EPA of the EPA Document Control Number for this submission.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,

C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosures

✓ FIED: CN989-85

TR91-641

AME Associates
BIOLOGICAL RESEARCH

PRINCETON PIKE, P. O. BOX 57 ■ PRINCETON, N. J. 08540 ■ TEL.: (609) 924-9658

Project #20-178

T-448

Primary Skin Irritation Study in Albino Rabbits with Tetraethyltin with Washoff

Conducted for

M & T Chemicals, Inc.
Rahway, New Jersey

Submitted by

AME Associates
Princeton, New Jersey

CAS: 597-64-8

A. M. E. ASSOCIATES P.O. BOX 57 PRINCETON, N. J. 08540

November 30, 1966

PROJECT #20-178

SPONSOR: M & T CHEMICALS, INC.

SUBJECT: Primary Skin Irritation Study in Albino Rabbits with Tetraethyltin with Washoff

OBJECTIVE

To determine the primary irritation potential of Tetraethyltin after an exposure period of five minutes followed by washoff.

MATERIAL

Tetraethyltin supplied by M & T Chemicals, Inc., for use in this study.

PROCEDURE

A group of six healthy albino rabbits (three males and three females) was employed in the project to study the experimental material. The hair was clipped from about the sixth thoracic vertebrae to the sacral region and about 4 inches from the vertebral column on each side using an electric clipper. Two areas, approximately 10 cm apart, on the back of each rabbit were selected as application sites. One site was abraded by making four epidermal incisions in a cross hatch pattern on this site. Patches consisting of two layers of

light gauze cut into squares (2.5 cm on each side) were secured to each of the two selected areas by strips of adhesive tape. A 0.5 ml portion of the experimental material was introduced under each patch. An intact and abraded site were treated on each rabbit.

The patches were removed after a five minute contact period and the sites were then washed using Zest soap. The sites were washed for a fifteen minute period alternating lathering and rinsing. After the washing was completed, the animals were dried and dry gauze patches were applied to the test sites. The trunks of the animals were then wrapped in gauze and taped during the next twenty-four hour period. At the end of the twenty-four hour period, the patches were removed and the patch sites were examined and evaluated. The sites were again examined seventy-two hours after application. The final score reported represents an average of the twenty-four and seventy-two hour readings.

The scoring method employed was that of Draize, Woodard and Calvery and is described by Draize on page 48 of "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" published by the Association of Food and Drug Officials of the United States.

Evaluation of Skin Reactions

(1) Erythema and Eschar Formation

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet red) to slight eschar formation (injuries in depth)	4
Total possible erythema score	4

(2) Edema Formation

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total possible edema score	4

RESULTS

Employing the procedure for conducting primary skin irritation studies utilizing albino rabbits as the test animal, M & T Chemicals, Inc., Tetraethyltin sample caused death in all rabbits within eighteen hours. During the period of time

preceding death, general observations showed deep depression, loss of reflexes, and lack of coordination. A slightly exaggerated response to pain was also noted.

CONCLUSIONS

Due to the very acute deaths of all rabbits with the Tetraethyltin sample, conclusions based on the usual parameters for evaluation of skin irritation could not be made.

SUBMITTED BY Russell S. Edmonds

AME ASSOCIATES

Russell S. Edmonds, V.M.D.

President

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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King of Prussia, Pennsylvania 19406-0018

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section (e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12672A

Triage of 8(e) Submissions

Date sent to triage: APR 20 1995

Submission number: 12672A

NON-CAP CAP

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 **pages** 1,2 **pages** 1,2 (abs)

Notes:

Contractor reviewer : PDR **Date:** 3/29/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1092 -12672 SEQ. A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: Elf Atochem North America, Inc

SUB. DATE: 10/12/92 OTS DATE: 10/26/92 CSRAD DATE: 02/09/95

CHEMICAL NAME:

CAS#
597-64-8

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)
DISPOSITION:
0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/USERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:

NON-CBI INVENTORY
YES
CAS SR NO
IN TERMINI

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER

SPECIES
RBT

TOXICOLOGICAL CONCERN:
LOW
MED
HIGH

USE:

PRODUCTION:

> <ID NUMBER>
8(e)-12672A

> <TOX CONCERN>
H

> <COMMENT>
ACUTE DERMAL TOXICITY IN RABBITS IS OF HIGH CONCERN BASED ON DEEP DEPRESSION, LOSS OF REFLEXES, LACK OF COORDINATION AND MORTALITY (3/3 M, 3/3 F) FROM A 5 MINUTE EXPOSURE TO 0.5 ML. BECAUSE OF DEATH WITHIN 18 HOURS, SKIN IRRITATION COULD NOT BE EVALUATED.